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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,783	07/02/2003	Thomas J. La Rosa	38-21(53373)A	2839

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EXAMINER	
BUI, PHUONG T	
ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/612,783	LA ROSA ET AL.	
	Examiner	Art Unit	
	Phuong T. Bui	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4 and 9-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 9-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's restriction election filed January 8, 2008. Applicant elects Group I and SEQ ID NO:3366 encoding SEQ ID NO:6915 without traverse. Claims 1, 2, 4 and 9-13 are pending and are examined in the instant application. This restriction is made FINAL.

Since SEQ ID NO:3366 was first disclosed in the instant application, Applicant date of priority benefit is July 2, 2003.

Claim Rejections - 35 USC § 112, second paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 2, 4 and 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, "complement" reads on a two nucleotide sequence, which does not appear to be Applicant's intention. In addition, the specification discusses several types of complements. It is suggested that Applicant inserts "full-length" before "complement" for clarification. All subsequent recitations of "complement" are also rejected. For examination purpose, the Office interprets "complement" as "full-length complement".

In claim 4, "substantially purified" is unclear. The specification gives examples of different levels of purity but does not define this term. It is suggested that Applicant amend "substantially purified" to "isolated". All subsequent recitations of "substantially purified" are also rejected.

In claim 4, "stringent conditions" is unclear because the specification gives examples of different hybridization conditions for stringent conditions but does not define this term. It is suggested that Applicant recites the desired hybridization conditions in the claim.

Clarification and/or correction are required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1, 2, 4 and 9-13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial, specific asserted utility or a well established utility. Applicant states that the claimed invention can be used to "impart unique genetic properties into transgenic plants" (p. 6), to improve properties of interest including yield, disease resistance, growth rate, stress tolerance (p. 8), and in recombinant DNA constructs, physical arrays of molecules, and as plant markers (p. 8). The claimed invention lacks substantial, specific utility for the following reasons. SEQ ID NO: 3366 was obtained from rice. Since all genes will "impart unique genetic properties" when expressed in a host, the claimed invention is generic to all genes and not specific to any particular gene. Thus, these asserted uses are not deemed substantial or specific to the claimed sequence. Similar, uses in "recombinant DNA constructs, physical arrays of molecules, and as plant markers" are generic to all genes or all plant genes and not specific to Applicant's claimed sequence. With regard to "yield, disease resistance, growth rate and stress tolerance", Applicant does not provide

any guidance as to how the claimed sequence can be used to achieve these properties. It is unclear whether the claimed sequence should be expressed, over-expressed or suppressed from expression to, for example, render the plant disease resistant or stress tolerant. It should be noted this is a rice gene, and rice plants naturally express this sequence and do not show increased yield, disease resistance, increased growth rate or stress tolerance. Thus, it is unclear how this sequence should be used differently to achieve a property not found in rice plants already expressing this gene. It is apparent that further research is required before the claimed polynucleotide would be of benefit to the public. However, the courts have decided that a utility which requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use lacks substantial utility.

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." (*Brenner v. Manson*, 383 U.S. 519 (1966)).

Thus, while regulating certain genes for certain traits such as disease resistance and stress tolerance would provide substantial benefit to the public, the claimed invention is not refined and developed to the point where specific benefit exists, as no guidance is provided as to how SEQ ID NO:3366 should be used to alter any specified plant trait. Accordingly, the claimed invention lacks substantial, specific asserted utility.

Additionally, there is no well-established utility for SEQ ID NO:3366 and a sequence encoding SEQ ID NO:6915. SEQ ID NO:3366 does not have a well-established utility for hybridization purposes because the encoded protein does not have utility for the reasons indicated above. Thus, for the reasons set forth, the claimed sequences lack utility (see Utility Examination Guidelines published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1092-1099).

Claim Rejections - 35 USC § 112, first paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 2, 4 and 9-13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial, specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Further, with regard to claims reciting sequences which hybridizes to SEQ ID NO:3366 and sequences having less than 100% sequence identity to SEQ ID NO:3366, these claims are further not enabled because they encompass unspecified base substitutions, deletions, additions, and/or combinations thereof without any recitation of function. Even if the claimed sequence confers stress tolerance or disease resistance when expressed, these claims are not enabled because Applicant provided no working example or guidance as to which region(s) of SEQ ID NO:3366 should be retained, which region(s) would tolerate mutations, or how one skilled in the art can predictably

and reliably make such determination without undue experimentation. While one skilled in the art can readily make mutations to SEQ ID NO:3366 or the sequence encoding SEQ ID NO:6915, further guidance is needed as to what mutations would not abrogate its function, which is undisclosed or unknown here. With regard to fragment, Applicant provided no working example of functional fragments or guidance as to how functional fragments can be determined without undue experimentation. Accordingly, Applicant has not enabled these sequences as commensurate in scope with the claims.

Moreover, with regard to claims reciting "hybridizes to stringent conditions" and "complement", if SEQ ID NO:3366 encodes a protein which has activity, a sequence which hybridizes to SEQ ID NO:3366 or a sequence which is a complement of SEQ ID NO:3366 would be the negative-sense strand in a double-stranded molecule and thus would not encode a protein and would not have activity.

For all the reasons set forth above, Applicant has not enabled the claimed invention.

8. Claims 4 and 9-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Sequences which “hybridize under stringent conditions” and sequences having less than 100% sequence identity lack adequate written description because Applicant does not disclose a representative number of species as encompassed by these claims.

The claims encompass mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The claims also encompass sequences from other species. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. Applicant discloses a single sequence SEQ ID NO:3366 isolated from rice. Thus, there are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants, allelic variants and sequences from other plants and organisms, absent further guidance. Accordingly, there is lack of adequate description to inform a skilled artisan that Applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/ Vol.66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 4 and 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Sasaki et al. (Accession No. AP004129, GenEmbl Database, 2001, Result 5 (U)). Fragment is defined in the specification as any 15 nucleotide sequence of SEQ ID NO:3366 having no specified function. For claims 4 and 9-12, it is also noted that the 15-mer nucleotide sequence does not have to be an exact match due to the hybridization and percent sequence identity language. Sasaki teaches a nucleotide

sequence obtained from rice having 72.9% sequence identity to SEQ ID NO:3366 and having at least 15 consecutive nucleotide sequence in common with SEQ ID NO:3366. Accordingly, Sasaki anticipated the claimed invention.

Remarks

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong T. Bui/
Primary Examiner, Art Unit 1638
03/03/08